



Calvary Automation Systems, Inc.



*Medical Devices*

# Software and Equipment Validation

## 21 CFR11 Validation

Controlled Criteria Parameter Management via login password authority to "Change-history" data files per 21 CFR Part 11.

Model Selection compliance with 21CFR Part 11 requirements for Access Authorization, Entry and Edit Tracking (time/date, author).

21 CFR Part 21 compliance via CTC PowerStation PC with InteractX software solutions:

- Enhanced system performance and functionality
- Development, programming and maintenance simplicity
- Standard peripheral device compatibility
- EtherNet and Serial Communication capabilities and compliance

## FDA Validation

FDA Software Validation and Documentation consistent with FDA requirements as follows:

- **Fault List Documentation:** List-format Identification of all potential station and system faults
- **Fault Condition Verification:** Functionality Fault Condition Verification with documented procedures and results
- **Reject Validation:** Induced System /Station Reject Conditions with documented procedures and results
- **Software Specification:** Creation and maintenance of software specifications in keeping with General Principles of Software Validation: Final Guidance for Industry and FDA Staff. January 11, 2002, US Department of Health and Human Services, Food and Drug Administration, Center for Devices and Radiological Health. Software Validation documents include:
  - **Reference Documents:** Technical documents as they pertain to communication devices including the standard Calvary Automation Controls Print Package.
  - **Software Development Requirements:** A definition of Controls Hardware and Software including limitations.
  - **Operational Description and Validation:** Descriptions and validations based on the program, code-section by code-section, and on a station-by-station basis.

## Category 3 and 4 Safety Designs

As a standard, many of Calvary Automation's long-term customers require Category 3 and 4 safety requirements compliant with specific safety and government regulatory safety requirements. Development of the specified requirements is based on specific customer requirements, our first-hand experience with Category 1 to 4 safety requirements, and the stringent requirements of CE standards for Europe.

- **Machine Guarding:** 29 CFR 1910.212 and ANSI B11.TR3
- **Machine Safety Risk Assessments:**
  - Preliminary Assessment** – to determine specific design criteria
  - Post-Build Assessment** – to determine conformance to specified safety criteria
- **Redundant Safety Circuits** with hard wired safety relays

## ATEX – Explosion Proof

**ATEX (Explosive Atmospheres) Directive 94/9/EC.**

This directive provides the technical Essential Health and Safety Requirements (EHSR's) and conformity assessments to be applied for equipment and protective systems intended for use in potentially explosive atmospheres. Three equipment pre-conditions that typically impose the application of the directives are:

- Equipment source of ignition**
- Explosive atmosphere of equipment environment**
- Atmospheric conditions of equipment**

## Clean Room Assembly

Calvary Automation provides design experience, capabilities and facilities to a Class 100 Clean Room environment including:

- In-House Class 10,000 Clean Room with HEPA Filtration
- Clean Room Mechanical Design Practices
- Laminar Air Flow Assembly Environments

## CE Certification

**Technical safety requirements of the following European Union directives:**

**Machinery Directive 98/37 EC:** Critical elements take into account potential hazards during operations and to exposed personnel. Areas covered include safety and reliability of control systems, required characteristics of guards and protection devices, maintenance, instructions manual, lighting, materials and products, and many other risks.

**Low Voltage Electrical Equipment Directive 73/23 EEC:** Addresses potential hazards during manufacture and operations, relating mainly to risks of electric shock and fire.

**Electromagnetic Compatibility (EMC) Directives 89/336 EEC:** Requirements are divided into two categories: **Emissions** and **Immunity**. Equipment must not emit unwanted electromagnetic pollution (interference). Due to certain amounts of electromagnetic pollution in the environment, this directive also states that the equipment must be immune to a reasonable amount of interference.

**Calvary Automation's typical services include:**

- Technical documentation and instruction manual review
- Risk analysis of equipment in accordance with the applicable directive and standards
- Technical solutions for identified non-conformities
- Preparation assistance with Technical File, Declaration of Conformity, and CE MARK requirements
- Electrical and EMC testing on your equipment at your facility
- Detailed ACC-APAVE examination and testing reports
- Purpose and description of assignment

## Material Passivation

Material Passivation is the process of iron/carbon removal from stainless steel welded joints to prevent oxidation and rust formation and is followed by an electro-polish process to brightly finish the surface.

**Passivating (v. pass-i-va-ting)** *The chemical treatment of a stainless steel surface with a mild oxidant such as a nitric acid or citric acid solution. Typically done to remove "free-iron" from the metal surfaces, which enhances the corrosion resistance of the stainless steel surface.*

**Electro Polishing (v. elec-tro pol-ish-ing)** *The reverse electrochemical process of electroplating. The electro polishing process smooths the microscopic surface of a metal object resulting in a metal surface that is microscopically featureless.*

## Data Collection

**Calvary Automation Performance and Data Tracking Utility** is provided with all Allen Bradley controlled standard equipment including:

- Standard Excel spread sheet-based utility
- PC-based running Windows 2000 or greater with EtherNet
- Displays and records live production data (*total good, total reject, total faults, average cycle time, total runtime, total downtime, total idle time, uptime, yield*) for each automation station
- Records alarm logs with associated stop time, start time, and durations
- Pareto chart reports

## Risk Assessment

Typically, a preliminary pre-build and a final post-build Risk Assessment is jointly achieved by Calvary Automation's mechanical and controls engineers in conjunction with the customer's assigned project team member(s):

**Preliminary Risk Assessment** will determine the specific machine safety design criteria and requirements.

**Post-build Risk Assessment** will determine conformance to the original criteria.

# Product Development

## Tip Forming

- Custom, precision-machined catheter tip punch and dies
- High-degree of polish with excellent release qualities
- Closed-loop temperature and servo-motion control
- Profile-specific punch and die forms (*formed to spec and cut to length*)
- Post-form vision inspection and measurement
- Multiple model and multiple gauge production capabilities
- Simultaneous engineering and product development



## 1-D Serial and 2-D Matrix Bar Code

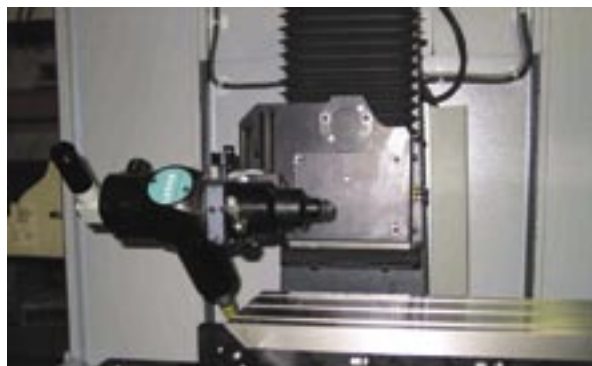


- Laser, Ink Jet, and Thermal Transfer bar code marking and validation
- Incoming component lot traceability
- Task-by-task assembly and test data association
- Managed model changeover with error-proofing
- Historic data archive and retrieval



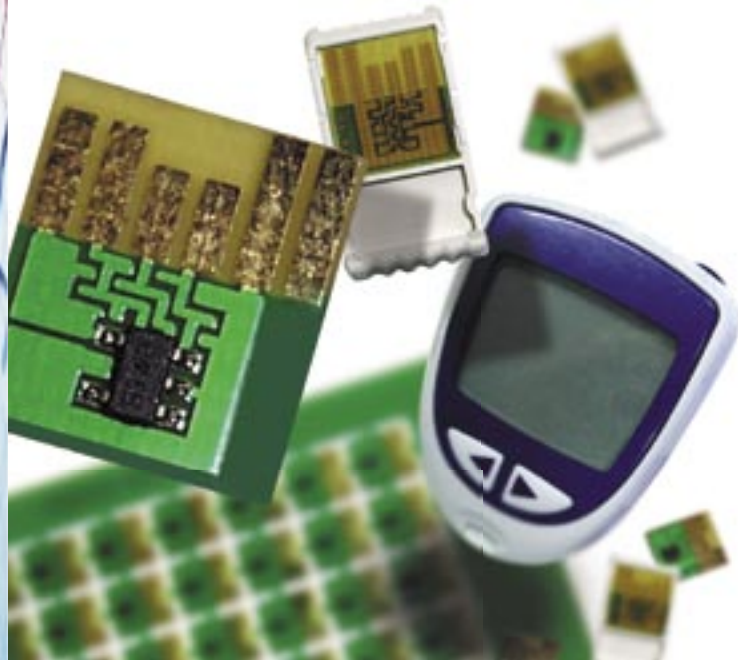
## Laser Welding

- YAG and CO2 laser welding, cutting, ablating and marking
- Fiber-optic and conventional beam delivery
- In-line camera viewing with focus adjustment capability and display monitor
- Fume extraction systems
- Auto-calibration routine with pass/fail feedback
- CDRH safety conformance and compliance
- Integrated laser and servo-motion delivery systems



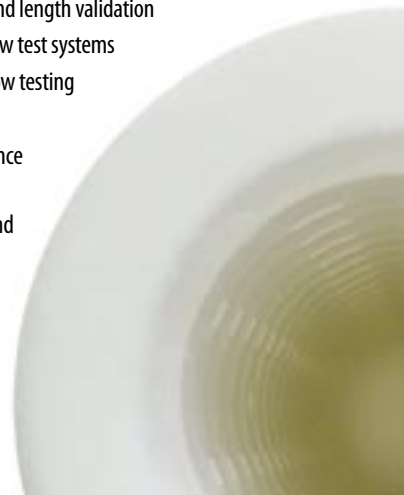
## Hand Held Device Assembly

- Standard modular assembly chassis's
- Small and mid-size diagnostic device assembly
- High-speed, high-accuracy, tight tolerances
- Non-marring handling and assembly practices
- Final product inspection for performance and appearance
- Multiple-model production capabilities
- Feeding, welding, depaneling, forming, pressing, potting, curing, etc.
- High-speed performance and characteristics testing



## Medical Grade Filters

- Semi and fully-automated filter assembly
- Precision filter end-trimming and length validation
- Single and multiple position flow test systems
- High-precision, low pressure flow testing
- Class 100 clean room assembly
- Explosion proof (ATEX) compliance and conformance
- Statistical data accumulation and reporting via LabView software





## Packaging and Assembly

- Full and semi-automatic transfer from assembly to packaging
- Carton, pouch, bag or sleeve erection, positioning and sealing
- Good part count validation and reject disposal
- Laser, ink-jet, or labeling for carton or case identification and validation
- Carton association to lot, assembly and test information
- Case assembly and palletizing

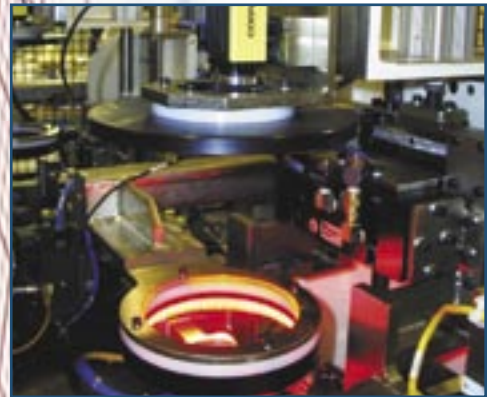


## Coatings and Treatments

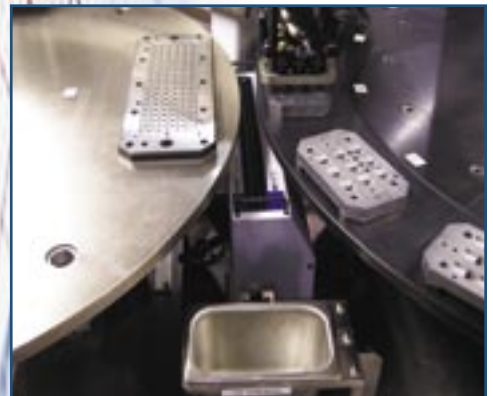
- Vibration-free dipping and medical coating equipment
- Smooth control of servo-driven motions
- Coating thickness uniformity, consistency and repeatability
- Medical-grade coatings for implant devices
- Volumetric validation by pre and post precision weigh testing
- Contact and non-contact coating deposition systems
- FDA approved plasma electrolytic depositions (PED)
- System design for materials compatibility



**Data Collection, Performance Tracking and Revision Management**



**Vision Inspection Systems**



**Cleanroom Environments**



**Robotics**

# Top 10

## Reasons to Choose Calvary Automation

Everyone at Calvary Automation appreciates the difficult nature of choosing a competent system integrator. We understand the importance of durable, quality equipment that is delivered on-time and within budget. So, why choose Calvary Automation?



### 1 Top Automation Engineering Talent

Calvary Automation possesses the top automation engineering talent in the Eastern United States. Seven of our staff engineers have served as chief engineers for some of the largest automation companies in the Northeast.

### 2 Detailed Project Management System

Our detailed project management system and methods, coupled with our detailed method of concept engineering and estimating, ensures that machines are designed, built, and qualified in a systematic, repeatable manner, each time, on every project.

### 3 On-Time Delivery Record

Although it sounds unreal, Calvary Automation possesses a near perfect On-Time Delivery Record. Our people, our experience, our management methods, our target of "Power-On" Milestone, have all been instrumental in achieving a 98% level of performance since 2001 which coincides with the implementation of our project management system.

### 4 First Run Acceptance Trials

Coupling our project management system, Milestone "Power-On" dates and an experienced staff of engineers and tool makers with performance tracking software has allowed Calvary to highlight this achievement. Performance in this category saves real time (Travel Time and Validation Labor) and real dollars (Travel and Living Expenses, Additional Run Off Parts, and Reduced Labor Expenses).

### 5 Free Performance Tracking Software

Not that anybody can't provide Performance Tracking Software with each Machine but Calvary Automation provides this tool free-of-charge. Performance tracking software provides information necessary for continuous improvement and includes a Pareto Fault Chart, Uptime/Downtime and Overall Throughput and Efficiency Calculations, Fault Lists, Scrap Rates and Good Part/Bad Part Lists. It also doubles as a Real Time, On-Line Diagnostic Tool.

### 6 Free Service to Preferred Customers

Calvary Automation provides free, periodic service to preferred customers for one year following shipment of each system that exceeds \$2,000,000. Service can consist of mechanical, electrical or programmatic maintenance, trouble shooting for station or system efficiency improvements, additional training, etc.

### 7 Financial Strength and Credit Rating

Calvary Automation has the highest A1 credit rating from Standards and Poor. Accounts payable average approximately 35 days. Financial strength is an extremely important characteristic as it helps ensure the highest caliber of employee talent as well as on-time delivery of commercially purchased components.

### 8 Top 100 Business Recognition

Calvary automation is recognized as one of the Top 100 Businesses (#46 and #37) in the Rochester, New York business community in 2003 and 2004. In fact, Calvary Automation was the only Automation System Integrator or Tool and Die-type company who made the list during both years.

### 9 Standard and Modular 3-D Designs

AutoCad 2D and SolidWorks 3D Design software are employed to achieve all mechanical equipment designs. Through the years Calvary Automation has built a considerable design library comprised of modular components designs that are used over and over again. Among the library's most commonly deployed design standards are: Aluminum and Steel Machine Bases, 2 and 3-Axis Pick-and-Place Units, Side-Docking Pallet Stops, Tray Feeders, and Controls Enclosures.

### 10 Medical Device Product Design and Software Experience

Since 1999, Calvary Automation continues to provide Medical Device Assembly and Test Systems for numerous and notable Medical and Health Diagnostic device suppliers. Medical Device assembly experience consists of: In-Vitro Diagnostic Tubes, Hand-held Diagnostic Devices, Pace Makers, Medical Coatings, Flexible Cannula Tipping, Medical Grade Filters and many others.





Calvary Automation Systems is recognized as a leading manufacturer of special machines, turnkey automated systems, and specialized fixturing. Our commitment to quality and fast response is the heart and soul of our business growth. We deliver machines, tooling and software solutions with quick delivery dates and difficult design tasks that most companies can't meet. We are a dedicated world-class and global supplier of a wide variety of automated machines and machined components. Many of Calvary Automation's customers are in the medical device, electronics, business machines, and automotive industries.

The focus on the customer's needs is fully supported by Calvary's sophisticated project management system, where emphasis is placed on communication throughout all phases of the project. From the design to the debug stage of equipment, customers are fully involved. Target dates are reviewed bi-weekly to ensure on time deliveries and job tracking is fully documented.

Our mission has always been to provide our customers with benchmark quality, cost, and delivery. We pride ourselves on providing exceptional service during and after product delivery.



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